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SUPREME COURT, U.S.

Nos. 07-521 & 07-525

IN THE
Supreme Court of the United States

WILLIAM J. CATALONA, ET AL.,
Petitioners,

v.

WASHINGTON UNIVERSITY,
Respondent.

RICHARD WARD, ET AL.,
Petitioners,

v.

WASHINGTON UNIVERSITY,
Respondent.

ON PETITIONS FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals correctly determined, as a matter of Missouri law, that research participants made an inter vivos gift of human blood and tissue samples to a University biorepository for prostate cancer research.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

INTRODUCTION 1

STATEMENT 3

REASONS WHY THE PETITIONS SHOULD BE DENIED 13

I. The Petitions Should Be Denied, On Multiple Grounds. 14

II. The Decision Of The Court Of Appeals Is Correct. 22

III. The Court Of Appeals' Decision Will Not Have Adverse Consequences 26

CONCLUSION 32

APPENDIX 1a

Letter from Ivor A. Pritchard, Ph.D. to Samuel L. Stanley, Jr., M.D. (Nov. 29, 2007). 1a

TABLE OF AUTHORITIES

Page(s)

CASES

Cardinale v. Louisiana, 394 U.S. 437 (1969) 16

Clippard v. Pfefferkorn,
168 S.W.3d 616 (Mo. Ct. App. 2005)..... 11, 12

Duvall v. Henke,
749 S.W.2d 714 (Mo. Ct. App. 1988)..... 11

Franklin v. Moss,
101 S.W.2d 711 (Mo. 1937) 12

Geier v. America Honda,
529 U.S. 861 (2000)..... 15, 25

Greenberg v. Miami Children's Hospital Research Institute, 264 F. Supp. 2d 1064 (S.D. Fla. 2003) 9, 19

Grimes v. Kennedy Krieger Institute, Inc.,
782 A.2d 807 (Md. 2001) 19

Hillsborough County v. Automated Medical Laboratories, 471 U.S. 707 (1985) 15, 25

Hines v. Davidowitz, 312 U.S. 52 (1941) 15, 25

Huddleston v. Dwyer, 322 U.S. 232 (1944)..... 14

Kraemer-Katz v. United States Public Health Service, 872 F. Supp. 1235 (S.D.N.Y. 1994) 20

Moore v. Regents of University of California, 793 P.2d 479 (Cal. 1990) 9, 18

Pilkington v. Wheat, 51 S.W.2d 42, 44 (Mo. 1932) 10

Wright v. Fred Hutchinson Cancer Research Ctr., 269 F. Supp. 2d 1286 (W.D. Wash. 2002) 21

REGULATIONS

45 C.F.R. § 46.101 30

45 C.F.R. § 46.102 ..... 3, 5, 30

45 C.F.R. § 46.109 ..... 3, 5, 28

45 C.F.R. § 46.116 ..... 5, 9, 17, 20, 22

45 C.F.R. § 46.117 5

45 C.F.R. § 46.407 19

OTHER AUTHORITIES

Carl H. Coleman, *Duties To Subjects In Clinical Research*, 58 Vand. L. Rev. 387 (2005) 26

Erica Heath, "The History, Function, and Future of Independent Institutional Review Boards," published in National Bioethics Advisory Commission, *Ethical And Policy Issues In Research Involving Human Participants*, Vol. II (2001) 5

Letter from F. William Dommel Jr., Director, Division of Compliance, Office for Protection from Research Risks to Merel F. Glauber, Office of General Counsel, University of California (Mar. 21, 1989) 23

Letter from Carol J. Weil, Compliance Oversight Coordinator, Division of Human Subject Protections, Office for Human Research Protections, to John C. McDonald, Chancellor/Dean, Louisiana State University Health Science Center Shreveport (Jan. 25, 2006), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR06/jan06a.pdf. 18

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Part A: Boundaries Between Practice and Research (April 18, 1979), *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm 27

Sup. Ct. R. 10 14

INTRODUCTION

Respondent Washington University respectfully opposes the Petitions for a Writ of Certiorari in this case. The court of appeals unanimously affirmed the district court's decision that, as a matter of Missouri property law, the University owns tissue and blood samples in the world's largest biorepository for prostate cancer research. Leading institutions and associations in the fields of medical research and higher education, including (among others) the American Cancer Society, the American Council on Education, the Association of American Medical Colleges, Johns Hopkins University, and the Mayo Clinic filed briefs as amici curiae in the court of appeals in support of the University, arguing that the position advocated by Petitioners would have profoundly harmful consequences for medical research.

The Petitions should be denied on multiple grounds:

First, the court of appeals decided an issue of state law. This Court rarely grants review of state law questions, and Petitioners have not even asked the Court to review the state-law issue in this case.

Second, the preemption question framed by the Petitioners was neither decided by nor properly presented to the courts below. Petitioners' briefs never mentioned the word "preemption." Instead, Petitioners told the courts they were "pressing state common law rights," not federal rights. Ward C.A. Reply Br. 12 n.6.

Third, the federal issue Petitioners seek to raise would not change the outcome of this case. The court of appeals found that there was ample evidence of donative intent apart from language challenged by Petitioners that appears in some of the informed consent documents, and thus the court had no need to decide whether the informed consent documents included so-called "exculpatory language" prohibited by federal regulations.

Fourth, there is no conflict in the circuits on the preemption question that Petitioners seek to raise or on the state property law issue that the courts below actually decided. Only a few courts have considered the issue of ownership of human tissues used for medical research, and they have reached exactly the same result as the courts in this case.

Fifth, the federal regulations on which Petitioners seek to base their preemption argument do not provide a private right of action. The Department of Health and Human Services ("HHS"), the federal agency that promulgated the regulations, has full authority to interpret, enforce, and amend the regulations. It has not endorsed Petitioners' preemption argument, and has recognized that individuals are permitted to donate human tissue for research purposes.

Sixth, the decision of the court of appeals is correct. Petitioners' preemption argument proves too much, because it would effectively prohibit donations of human biological materials for medical research. Neither Congress nor the agency could have intended this result, and in fact the agency has

stated that its regulations do not prohibit human tissue donations for research purposes.

Seventh, the court of appeals' decision does not alter existing law, and will not have the adverse consequences predicted by Petitioners and their amicus. To the contrary, it is Petitioners' position that would harm medical research by inhibiting researchers from sharing samples and encouraging efforts to divert samples away from basic medical research into for-profit activities. Petitioners seek to raise issues that are not presented by the facts of this case, and in doing so ignore the fact that the University's use of samples is comprehensively regulated by a federal agency and an Institutional Review Board required by federal regulations. See 45 C.F.R. §§ 46.102, 46.109.

For each of these reasons, the Petitions should be denied.

STATEMENT

1. Respondent Washington University is a leading private research university in St. Louis, Missouri. Pet. App. 3a, 22a.[1] The University's Medical School includes a Division of Urologic Surgery that conducts research on urologic diseases such as prostate cancer. *Id.* at 4a.

Petitioner William Catalona, a leading prostate cancer surgeon, was employed by Washington University from 1976 to 2003 and served

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[1] References to "Pet. App." refer to the appendix to the Catalona Petition, No. 07-521.

as Chief of the Division of Urologic Surgery from 1984 to 1998. Pet. App. 4a. In 1983, Dr. Catalona and his colleagues began collecting human tissue samples for use in prostate cancer research. *Id.* Over a period of years, this collection grew to become the world's largest biorepository of human blood and tissue samples for prostate cancer research. *Id.* The biorepository contains approximately 3,500 prostate tissue samples from patients of University physicians including Dr. Catalona. *Id.* at 7a. It also includes approximately 100,000 blood samples, most of which were donated by volunteers who were not patients of any University physician. *Id.* In addition to blood and tissue samples, the biorepository includes DNA samples donated by patients of various University physicians and their relatives. *Id.* Of the approximately 30,000 individuals who contributed samples to the biorepository (known as "research participants" or "RPs"), no more than 10 percent were patients of Dr. Catalona. *Id.*

The biorepository is housed in University buildings, administered by University employees, and funded primarily with University money. Pet. App. 4a. The University has exercised exclusive control over the samples, and is solely responsible for deciding who can access and use the biorepository. *Id.* at 4a, 24a.

The University's use of samples in the biorepository is supervised and regulated by a federal agency, the Office for Human Research Protections ("OHRP") within HHS. HHS has promulgated federal regulations, known as the "Common Rule," that govern the conduct of federally-funded human subject research. The Common Rule

requires the University to obtain informed consent from individuals who donate tissue samples for use in medical research. *See* 45 C.F.R. §§ 46.116, 46.117. In addition, the University is required to establish an Institutional Review Board ("IRB") to review and approve research protocols. *See* 45 C.F.R. §§ 46.102; 46.109; *see generally* Erica Heath, "The History, Function, and Future of Independent Institutional Review Boards," published in National Bioethics Advisory Commission, *Ethical And Policy Issues In Research Involving Human Participants*, Vol. II (2001).

RPs contributing samples to the biorepository signed consent documents that typically bore the University Medical Center's logo and used the term "donation" to describe the transfer of the sample. Pet. App. 5a. The consent document and a University brochure explained that biological samples "may be used for research with our collaborators at [the University], other institutions, or companies." *Id.* The documents typically stated that, by participating, the RP "make[s] a free and generous gift of your [blood, tissue, and/or DNA] to research that may benefit others." *Id.* at 26a. RPs were informed that they could not "claim ownership rights to any medical or scientific product that results from research with your tissue." *Id.* at 6a. The informed consent documents stated that the collection of samples is for medical research and not for patient care. *Id.* at 26a.

Dr. Catalona and other Washington University physicians have conducted numerous prostate cancer research studies using samples from the biorepository. Pet. App. 4a-5a. Dr. Catalona was

designated as the principal investigator for some but not all of the research studies. *Id.* When Dr. Catalona was listed as principal investigator, the informed consent documents stated that the research study would be conducted by Dr. Catalona "and/or colleagues." *Id.* at 42a. Other research institutions requested and received samples from the biorepository to conduct research projects either in partnership with or independent of the University. *Id.* at 7a. While employed at the University, Dr. Catalona repeatedly transferred biorepository materials to other research institutions pursuant to material transfer agreements (MTAs). *Id.* Numerous MTAs signed by Dr. Catalona acknowledge the University's ownership of the biological samples. *Id.* The MTAs are in accordance with the University's written Intellectual Property Policy, which provides that tangible research property is owned by the University. *Id.* at 16a n.8.

2. In early 2003, Dr. Catalona accepted a position at Northwestern University. Pet. App. 7a. On February 18, 2003, he sent a letter to all RPs who had contributed samples to the biorepository (including many RPs who had never been his patients) informing them of his planned departure from the University, his continued availability for consultation and treatment, and his plans for prostate cancer research. *Id.* The letter states "[y]ou have entrusted me with samples, and I have used them in collaborative research that will help in your future medical care." *Id.* at 33a. Attached to the letter was a "Medical Consent & Authorization" form for the RPs to sign and return. The form stated: "Please release all of my samples to Dr. Catalona at

Northwestern University upon his request." *Id.* Approximately 6,000 RPs returned the completed form to Dr. Catalona; about 24,000 RPs did not. *Id.*

At the time Petitioner Catalona sent the letter and release form, he was an employee of the University. Pet. App. 33a-34a. He did not obtain approval from the University's Institutional Review Board ("IRB") (or the IRB at Northwestern University) to send the letter or the release form. *Id.* at 34a.

3. This case began after Dr. Catalona contacted the National Cancer Institute to warn them that he was disputing ownership rights to samples in the prostate cancer biorepository. University C.A. App. 2:256-57 & 3:553.[2] As a result of Dr. Catalona's action, NCI returned to the University more than 400 samples from the biorepository that were to be used in research intended to develop an improved test for prostate cancer. *Id.*

In August 2003, the University filed a declaratory judgment action seeking to confirm its ownership of the blood and tissue samples in the biorepository. Pet. App. 9a. The University's four-count complaint raised three state law claims and a claim under the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") that was abandoned prior to a ruling by the district court. University C.A. App. 5:1002-18.

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[2] References to "University C.A. App." refer to the appendix to Respondent's brief filed in the Eighth Circuit.

Petitioner Catalona filed a six-count counterclaim raising five state-law claims and a claim for a "violation of free speech" that he did not pursue. Neither the University's complaint nor Dr. Catalona's counterclaim mentions preemption. University C.A. App. 5:1002-18, 1033-58.

Dr. Catalona asked the court to issue an order prohibiting the University from using, transferring, or destroying tissue samples in the biorepository during the pendency of the litigation. Pet. App. 9a. The district court issued the order the next day, but subsequently withdrew it on the ground that it amounted to a preliminary injunction, and scheduled a hearing on whether to issue a permanent injunction. *Id.*

In February 2005, the court granted the motion of the Ward Petitioners, all of whom were RPs and patients of Dr. Catalona, to intervene in the case as defendants. The Ward Petitioners' answer and affirmative defenses likewise did not mention federal preemption. University C.A. App. 6:1355-65.

Following a three-day hearing, the district court (E.D. Mo., Limbaugh, J.) denied Petitioner Catalona's motion for a permanent injunction and entered judgment for the University. Pet. App. 19a-57a. The district court found that the University has been in exclusive possession of the biological materials at all times, has exercised exclusive control over the materials, and has continually asserted its ownership interest in the materials. *Id.* at 35a-37a. The court agreed with two prior cases holding a research participant to be a "'donor' who had parted with any semblance of ownership rights once their biological materials had been excised for medical

research." *Id.* at 41a (citing *Moore v. Regents of Univ. of California*, 793 P.2d 479, 487, 488-89 (Cal. 1990); *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003)). In addition to holding that the University is the owner of the biological materials under Missouri law, the court held that the RPs had made an *inter vivos* gift of the materials to the University and had not entered into a bailment. *Id.* at 41a-49a.

The district court determined that the informed consent documents signed by the RPs complied with a provision in the federal Common Rule barring "exculpatory language through which the subject or the representative is made to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." Pet. App. 44a, quoting 45 C.F.R. § 46.116. Relying on expert testimony, the court found that the research community understands this provision to prohibit language in informed consent documents that amounts to a release from malpractice or negligence, and that there is no such language in the University's informed consent documents. Pet. App. 45a. The district court also held that the RPs' right to discontinue participation in the research does not include "a right to control the disposition and use of the excised biological materials." Pet. App. 46a-47a.

The district court further found that Dr. Catalona's "Medical Consent and Authorization" form sent to RPs had not been properly approved by an IRB and did not constitute informed consent. Pet. App. 51a. The court commented that "the context in

which this form was sent is troubling" and "smacks of undue influence." *Id.* at 51a-52a.

The court noted that the biorepository is subject to "a 'check and balance' system" that monitors use of the materials for research and protects the safety and welfare of RPs. Pet. App. 52a. The court observed, "Medical research can only advance if access to these materials to the scientific community is not thwarted by private agendas." *Id.* Under Petitioners' proposed approach, research institutions could no longer rely on aggregate collections of biological materials, because "samples would come and go." *Id.* at 53a. In this situation, "[i]t would no longer be a question of the importance of the research protocol to public health, but rather who can pay the most." *Id.* at 52a.

3. The Eighth Circuit (Wollman, Riley, Shepherd, JJ) affirmed. Pet. App. 1a-18a. The court of appeals held that "[u]nder the facts of this case," individuals who make an informed decision to contribute biological materials to a research institution for medical research do not retain an ownership interest that allows them to direct that the materials be transferred to a third party. *Id.* at 11a. To decide this issue, the court "look[ed] to the substantive law of Missouri." *Id.* Missouri law defines an *inter vivos* gift as "'a voluntary transfer of property by the owner to another, without any consideration or compensation as an incentive or motive for the transaction.'" *Id.* (quoting *Pilkington v. Wheat*, 51 S.W.2d 42, 44 (Mo. 1932)).

Under Missouri law, the party claiming an inter vivos gift has the burden of showing, by clear and convincing evidence: "(1) present intent of the

donor to make a gift, (2) delivery of the property by the donor to the donee, and (3) acceptance of the gift by the donee, whose ownership takes effect immediately and absolutely." Pet. App. 11a-12a (citing *Clippard v. Pfefferkorn*, 168 S.W.3d 616, 618 (Mo. Ct. App. 2005)). The court found that the second element "unquestionably" was satisfied in this case, and therefore it focused on the other two requirements. *Id.*

The court noted that "[n]o specific language is required to reflect the donor's present intent to make a gift," and such an intent may be inferred from the surrounding circumstances. Pet. App. 12a (citing *Duvall v. Henke*, 749 S.W.2d 714, 716 (Mo. Ct. App. 1988)). The court of appeals agreed with the district court that "the circumstances surrounding the RPs' decisions to participate in genetic cancer research demonstrate the status of the RPs as donors." *Id.* That evidence included the following: (i) RPs were required to read and sign a consent document that bore the University's logo and described the RPs' participation as a "donation" of tissue or blood samples; (ii) RPs received a brochure that described the donations as "a free and generous gift of [biological materials] to research that may benefit society"; and (iii) RPs were specifically informed that their samples "may be used for research with our collaborators at [the University], other institutions, or companies." *Id.* at 5a, 12a-13a. In addition, the University's Intellectual Property policy provides that "tangible research property" "shall be owned by the University," and Dr. Catalona signed numerous documents acknowledging that the University is the owner of the samples in the biorepository. *Id.* at 15a-

16a & n.8. Moreover, Dr. Catalona routinely ordered that samples be destroyed to free up storage space, without obtaining additional consent from RPs. *Id.* Because the court of appeals was persuaded that this evidence demonstrated that the RPs intended to make an *inter vivos* gift to the University, it found it unnecessary to consider the validity or effect of additional language in some of the consent documents which stated: "By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate." Pet. App. 15a n7.

The court of appeals also held that the University had accepted the RPs' gift. The court noted that, under Missouri law, a gift "may be subject to a condition allowing the donor to exercise a particular revocation right in the future." Pet. App. 14a (citing *Clippard*, 168 S.W.3d at 619; *Franklin v. Moss*, 101 S.W.2d 711, 714 (Mo. 1937)). If that were not so, the court observed, many charitable donations would be impossible. Here, RPs may decline to answer additional questions or provide additional samples, may request that their donated biological materials no longer be used for medical research and (in some consent documents) may request that donated samples be destroyed. Pet. App. 14a. The court concluded: "[I]t is evident that the RPs did not retain the right to revoke and physically repossess the donated biological materials. Nor did the RPs retain the right to direct or authorize the use, transfer, or destination of the biological materials after their donation." *Id.* at 15a.

The court found no evidence that RPs were told that they could request the return of donated

samples. To the contrary, RPs who underwent surgery signed surgical consent documents providing that tissues removed during surgery and not used for clinical purposes would be destroyed as hazardous medical waste. Pet. App. 16a-17a. In addition, returning samples to RPs would violate state and federal laws governing the disposal of hazardous substances and infectious waste. *Id.* at 16a.

4. Petitioners filed an application to stay the Eighth Circuit's mandate pending the filing and disposition of a petition for a writ of certiorari. The Eighth Circuit stayed its mandate only for a period of 30 days to allow Petitioners time to seek a stay from this Court. In August 2007, Justice Alito, as Circuit Justice for the Eighth Circuit, denied Petitioners' application for a stay.

REASONS WHY THE PETITIONS SHOULD BE DENIED

There are multiple reasons for denying the petitions for certiorari in this case: the court of appeals decided an issue of state law; the preemption issue that Petitioners seek to raise in this Court was not properly raised or decided in the courts below; the preemption issue would not change the outcome of this case; there is no conflict in the circuits; and the federal regulations cited by Petitioners do not create a private right of action, and the federal agency that enforces the regulations has taken no position on Petitioners' preemption argument. In addition, the decision of the court of appeals is correct and will not have the adverse consequences suggested by Petitioners and their amicus. To the contrary, adopting Petitioners' position would significantly harm medical research.

I. The Petitions Should Be Denied, On Multiple Grounds.

1. The court of appeals held, as a matter of state law, that the RPs made *inter vivos* gifts of blood and tissue samples to the University. In deciding that question, the court "look[ed] to the substantive law of Missouri." Pet. App. 11a. The court's decision relies entirely on decisions of Missouri state courts applying Missouri state law. *Id.* at 11a-14a. The court of appeals did not decide any federal question, let alone a preemption question. To the contrary, the court expressly found "it unnecessary to address" the meaning or effect of a provision in a federal regulation that prohibits "exculpatory language" in informed consent documents. *Id.* at 15a n.7. The court explained that there was no need to decide this issue because other evidence "convinces us the RPs intended to make inter vivos gifts of their materials." *Id.*

This Court rarely grants a petition for certiorari to review an issue of state law. *See Huddleston v. Dwyer*, 322 U.S. 232, 237 (1944) ("[O]rdinarily we accept and therefore do not review, save in exceptional cases, the considered determination of questions of state law by the intermediate federal appellate courts."); *see also* Sup. Ct. R. 10(c) (Court may grant review to decide "an important question of *federal* law") (emphasis added). Indeed, Petitioners do not even ask this Court to review the state law issue decided by the courts below. That issue plainly warrants no further review.

2. Petitioners acknowledge that the federal preemption question they are asking this Court to

decide was neither addressed nor decided by the court of appeals. *See* Catalona Pet. 14 (court of appeals "refus[ed] to address" preemption argument); Ward Pet. 11 (court of appeals' refusal to address preemption argument was "inexplicable"). In fact, the lower courts did not decide a federal preemption question because Petitioners failed to raise it.

The word "preemption" did not appear anywhere in any of Petitioners' briefs filed in the court of appeals or the district court. Nor did Petitioners cite *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707 (1985), *Hines v. Davidowitz*, 312 U.S. 52 (1941), *Geier v. America Honda*, 529 U.S. 861 (2000), or any of the other federal preemption cases cited in their petitions to this Court. Instead, Petitioner Catalona stated that "Missouri law govern[s] the issue of ownership at stake in this case." Catalona C.A. Br. 15. The Ward Petitioners stated: "Missouri law determines who owns the Patient Tissue," and "Missouri common law and statutes control. On this the parties agree." University C.A. App. 6:1490. Petitioners expressly told the court of appeals that they were "pressing state common law rights" rather than any rights created by federal law, and that federal regulations merely "provide[] an interpretive guide in this case rather than an independent basis for the RPs' rights." Ward C.A. Reply Br. 12 n.6. Petitioners' statements to the lower courts tracked their legal claims, which rested entirely on state law (except for a First Amendment speech claim that Petitioners abandoned). University C.A. App. 5:1003; 5:1049-

51.[3] Although Petitioners now assert that they raised the preemption issue in the lower courts, the record shows otherwise.

This Court generally does not grant review of questions that were not properly presented to the courts below. Where a question has not been properly raised in the court below, "the record is very likely to be inadequate." *Cardinale v. Louisiana*, 394 U.S. 437, 439 (1969). A different rule would allow litigants to sandbag the lower courts and deprive this Court of the benefit of the lower courts' analysis of the issue. Accordingly, the Court should decline Petitioners' invitation to decide a preemption issue that was neither decided nor properly presented to the courts below.

3. Petitioners' argument would not change the outcome of this case. In the court of appeals, Petitioners cited the Common Rule in an effort to neutralize statements in some of the informed consent documents that "[b]y agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate." Pet. App. 15a n.7. Petitioners contended that this language was contrary to a provision of the Common Rule stating that informed consent forms may not contain "any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or

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[3] In the lower courts, Petitioners argued that the samples are governed by Missouri's law of bailments. That argument is inconsistent with Petitioners' current argument that federal regulations displace state property law.

appears to release the investigator, the sponsor, the institution or its agents from liability for negligence." 45 C.F.R. § 46.116. The court expressly held that it had no need to consider whether the language at issue was permissible under the Common Rule, because other "circumstances surrounding the RPs' voluntary decision to donate their biological materials" independently "convince[] us the RPs intended to make inter vivos gifts of their materials." Pet. App. 15a n.7. *See also id.* at 12a ("No specific language is required to reflect the donor's present intent to make a gift; in fact, the circumstances surrounding the contribution may create an inter vivos gift.") (citation omitted). Here, the circumstances surrounding the contribution included the facts that samples may be consumed during research and shared with other researchers, the limitations imposed by laws governing the disposal of medical waste, and the RPs' testimony that they had no expectation the samples would ever be returned to them. *See* Pet. App. 50a (no evidence that any of the RPs informed the University that they wanted the samples returned; RPs "could not have had a reasonable expectation of restoration" because of laws governing the disposal of medical waste); University C.A. App. 2:78 (Petitioner Ward's testimony that he did not expect tissue to be returned).[4]

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[4] If an informed consent document contains "exculpatory language," the remedy is to strike the exculpatory language, not to set aside the consent or the gift. In the few instances in which OHRP has determined that an informed consent document includes exculpatory language, it has simply directed (...continued)

4. There is no conflict in the courts of appeals on *either* the state law issue that the courts actually decided or the federal preemption issue that Petitioners now seek to raise. Only two other published decisions have addressed ownership of human tissue used in medical research, and both decisions reach exactly the conclusion that the Eighth Circuit reached here: research participants do not continue to own human tissues removed from their bodies and used for medical research.

In *Moore v. Regents of University of California*, 793 P.2d 479, 487, 488-89 (Cal. 1990), the California Supreme Court rejected the plaintiff's contention that "he continued to own his cells following their removal from his body, at least for the purpose of directing their use." The court found that the plaintiff, like the RPs here, "clearly did not expect to retain possession of his cells following their removal." *Id.* at 489. The *Moore* court, like the court of appeals in this case, recognized that state statutes governing medical waste severely restrict "a patient's control over excised cells," and thus eliminate "many of the rights ordinarily attached to property." *Id.* at 489, 492. The California Supreme Court held that the plaintiff had cognizable legal claims arising out

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that the waiver language be removed from the document. *See* Letter from Carol J. Weil, Compliance Oversight Coordinator, Division of Human Subject Protections, Office for Human Research Protections, to John C. McDonald, Chancellor/Dean, Louisiana State University Health Science Center Shreveport (Jan. 25, 2006), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR06/jan06a.pdf.

of the special circumstances of that case, but they did not include a claim to ownership of the cells.

Moore is particularly instructive because the plaintiff had a considerably *stronger* argument than the Petitioners in this case. Unlike the Ward Petitioners, the plaintiff in *Moore* was not informed that the tissues removed from his body would be used for medical research, and he did not consent to any research. Moreover, the physician in *Moore* sought to profit financially from research conducted with the plaintiff's tissues. In contrast, the RPs in this case gave their informed consent to use of the blood and tissue samples for prostate cancer research, and, far from profiting, the University has expended substantial amounts of money to develop and maintain the biorepository as a resource for prostate cancer researchers.

In the only other reported decision on point, the court reached the same result, holding that RPs "have no cognizable property interest in body tissue and genetic matter donated for research." *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003). The court concluded that the RPs' "property right in blood and tissue samples . . . evaporates once the sample is voluntarily given to a third party." *Id.* at 1075.

Tellingly, Petitioners do not cite *Moore* or *Greenberg*. Instead, Petitioner Catalona relies on two cases that obviously do not conflict with the decision in this case. In *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807 (Md. 2001), the court did not decide a preemption issue or any issue involving ownership of human tissues used for medical research. Instead, the court held that

parents and other surrogates generally cannot consent to the participation of a child in nontherapeutic research in which there is a risk of injury or damage to the health of the child. In so holding, the court noted that the researchers were obligated to obtain informed consent pursuant to 45 C.F.R. § 46.407, and concluded that this federal duty "translates into a duty of care" under state law. *Id.* at 849. The issue decided in *Grimes* is not the issue in this case, and there is no conflict between the two decisions.

The same is true of *Kraemer-Katz v. United States Public Health Service*, 872 F. Supp. 1235 (S.D.N.Y. 1994). *Kraemer-Katz* (which is a district court decision, and so could not give rise to a circuit conflict in any event) did not address ownership of human tissues used for medical research. Instead, it involved terminating the administration of an investigational drug to a patient involved in a study of its possible use as a treatment for osteoporosis. The court noted that 45 C.F.R. § 46.116(b)(2) establishes requirements for notifying research participants of the anticipated circumstances in which the subject's participation may be terminated without regard to the subject's consent, and observed that a state law that prohibited termination even when federal regulatory requirements are met would be preempted. *Id.* at 1240. As in *Grimes*, the court was discussing a different issue, and there is no conflict with the decision in this case.

5. An additional consideration weighing against certiorari is the absence of a private right of action to pursue violations of the Common Rule. OHRP, the federal agency that enforces the Common

Rule, "is responsible for the oversight of compliance by [the University] and all other federally-funded institutions engaging in human-subject research studies." Pet. App. 27a. OHRP has broad powers to enforce the Common Rule, including authority to suspend research projects and recommend that institutions or investigators be debarred from all government-funded studies. HHS, OHRP, "OHRP's Compliance Oversight Procedures for Evaluating Institutions" 5-7 (Oct. 19, 2005), *available* at www.hhs.gov/ohrp/compliance/ohrpcomp.pdf.

Petitioners acknowledge that there is no private right of action for violation of the Common Rule. *See* Ward Pet. 9 n.2; *see also* Catalona C.A. Reply Br. 6, 23 ("[T]he Common Rule provides no private right of action."); *see Wright v. Fred Hutchinson Cancer Research Ctr.*, 269 F. Supp. 2d 1286, 1289 (W.D. Wash. 2002). In the court of appeals, Petitioners argued that the absence of a private right of action under the Common Rule is not fatal to their claims because they "are pressing state common law rights," not federal rights. Ward C.A. Reply Br. 12 n.6.

Petitioners' assertion that the absence of a private right of action under the Common Rule should not detract from their preemption argument misses a basic point: OHRP has ample authority to enforce its rules and to address any conflicts that it perceives between its regulations and state law. This Court should not grant review of a preemption question before the agency itself has expressed a view as to whether its regulations preempt state property law (and before any lower court has ruled on the agency's position).

II. The Decision Of The Court Of Appeals Is Correct.

Neither Petition challenges the panel's unanimous affirmance of an experienced district judge on an issue of Missouri state law. The courts below analyzed the elements of an *inter vivos* gift under Missouri law and held that there was a gift based on extensive evidence of donative intent, delivery, and acceptance of the blood and tissue samples. Pet. App. 11a-17a.

The court of appeals held that the evidence of an *inter vivos* gift was so extensive that it was unnecessary to rely on statements in some of the informed consent documents that the RP waived "any claim you might have to the body tissues you donate," and thus unnecessary to consider whether that language is "exculpatory" within the meaning of the Common Rule, 45 C.F.R. § 46.116. If the court of appeals had reached that question, however, it would likely have agreed with the district court that the language is permissible under the federal regulations. The ordinary meaning of the term "exculpatory" is "clearing or tending to clear from alleged fault or guilt." Black's Law Dictionary 608 (6th ed. 2004). This ordinary meaning is consistent with the regulation's express prohibition of "releases . . . from liability for negligence." 45 C.F.R. § 46.116.

Disregarding the ordinary meaning of "exculpatory," Petitioners take the position that federal regulations prohibit RPs from relinquishing *any* legal rights whatsoever in an informed consent document. This is absurd. The most basic right of an RP is not to participate in medical research. If RPs cannot relinquish this basic right by signing an

informed consent form, then medical research is impossible. Moreover, samples may be consumed in the course of research (and may be discarded, as some were by Dr. Catalona, if they are no longer useful for research). A right to repossess the samples on demand would call into question a fundamental assumption of research, that researchers may consume donated samples.

It is inconceivable that HHS, the federal agency that promulgated the Common Rule, intended to outlaw medical research using human tissues. If it intended such an extreme result, the agency would have announced its position directly rather than indirectly through a prohibition on "exculpatory language" in informed consents. In fact, OHRP has expressly stated that its "regulations are not intended to prohibit the informed subject from making a legitimate donation of his or her cells or future derivatives of those cells." University C.A. App. 6:1309-11 (Letter from F. William Dommel Jr., Director, Division of Compliance, Office for Protection from Research Risks [the predecessor of OHRP] to Merel F. Glauber, Office of General Counsel, University of California (Mar. 21, 1989).[5]

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[5] OHRP's Acting Director recently sent a letter to the University's Vice Chancellor for Research "in order to assist Washington University and its institutional review board in its future consideration of research informed consent language." Letter from Ivor A. Pritchard to Samuel L. Stanley, Nov. 29, 2007. In the letter (which is reproduced as an appendix to this brief), "OHRP agrees with the district court that its guidance document on exculpatory language does not have a legally binding effect upon entities regulated by OHRP." App., *infra*, 4a. OHRP confirms that it conducted a compliance oversight (...continued)

Petitioners' reliance on the "exculpatory language" provision of the Common Rule fails for an additional reason as well. The Common Rule sets out the requirements for informed consent in federally-funded research involving human subjects. The Common Rule, including the exculpatory language prohibition, does not address ownership and confers no ownership rights on RPs. Instead, the exculpatory language prohibition addresses waivers of rights derived from some other source of law, such as state law. The OHRP guidance document Petitioners cite likewise refers to "property rights I *may* have . . . in tissue samples," without taking a position on whether RPs actually have such rights. As Petitioners' own expert acknowledged, a prohibition against disclaiming a right does not imply the existence of an underlying right.

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investigation in 2000 and made no finding that the University's informed consent documents contain exculpatory language. The letter clarifies that, "except in jurisdictions in which it has been conclusively determined that all research subjects have no legal rights in their excised human biological material," when OHRP conducts compliance oversight investigations it will find language included in OHRP's guidance document that waives such rights to be exculpatory. *Id.* Accordingly, OHRP asks the University to "ensure that any such language is removed from consent documents currently used at Washington University." *Id.*

OHRP's letter does not take the position that the Common Rule preempts any state laws. To the contrary, it looks to state law as the possible source for individual legal rights in excised tissue. *Id.* Moreover, OHRP's letter demonstrates that it is fully capable of interpreting and enforcing its own regulations (and amending them if necessary). The letter thus provides further confirmation that review by this Court is not warranted.

University C.A. App. 1:189-90. For example, the exculpatory language provision precludes waivers of negligence claims, but does not create any such claims or divest the research institution of its defenses to such claims under state law. For a variety of reasons, including laws governing the disposal of medical waste, individuals generally cannot claim ownership rights in blood and tissue that has been removed from their bodies during medical procedures, even when the patient does not make an express donation. Individuals are safeguarded through laws protecting their privacy and requiring informed consent to medical research, not by giving them continued dominion and control of tissues under state property law.

In short, the Common Rule and state property law address distinct subjects, and thus do not conflict. The federal regulations deal with experimentation on human subjects, not ownership of tissue. Rather than preempting state property law, the Common Rule operates as a separate body of rules governing federally-funded research. In this respect, the Common Rule is like the federal environmental laws that impose restrictions on the use of real property but do not displace state property law.[6]

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[6] Because there is no conflict between the Common Rule and state law, this case is unlike *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), or *Hines v. Davidowitz*, 312 U.S. 52 (1941). In *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985), the Court held that regulations promulgated by the Food and Drug Administration did *not* preempt local laws regulating blood plasma centers. Here, as in *Hillsborough*, the federal agency has not indicated (...continued)

III. The Court Of Appeals' Decision Will Not Have Adverse Consequences.

There is no factual or legal basis for Petitioners' assertion that the court of appeals' decision will have adverse consequences for RPs and medical research. The decision in this case does not change preexisting law, which provides multiple layers of protection for RPs. As explained in the amicus briefs filed in the court of appeals by the American Cancer Society, the Association of American Medical Colleges, the Mayo Clinic, and others, it is the position advocated by Petitioners that would cause profound damage to medical research, by making it difficult or impossible for researchers to share samples, and by making biorepositories vulnerable to attack by for-profit entities.

1. For good reason, Petitioners have largely abandoned the argument, made in their unsuccessful stay application to this Court, that all samples in the biorepository must be preserved for possible clinical use by RPs and their families. That argument ignored the fundamental requirement that investigators draw a bright line between medical research and clinical treatment, to ensure that RPs do not erroneously believe their participation in research will affect their clinical care. *See e.g.*, Carl H. Coleman, *Duties To Subjects In Clinical Research*,

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that its regulations are intended to be exclusive, or conflict with state law.

58 Vand. L. Rev. 387 (2005).[7] Consistent with this requirement, no RP testified that he expected to receive any clinical benefit from his participation in these studies. To the contrary, the district court found that the University's brochures and informed consent documents specifically informed RPs that they would *not* receive any direct benefit from their participation Pet. App. 25a; University C.A. App. 3:677; 4:931. Moreover, the RPs were informed that samples could be consumed during research, and they thus had no expectation that the samples would be preserved for clinical purposes.

In fact, the record demonstrates that samples in the biorepository are highly unlikely to be of clinical benefit to RPs or their families. Dr. Catalona could recall only a single instance in his decades at the University in which any of the tens of thousands of tissue samples in the biorepository was requested for a clinical purpose. University C.A. App. 2:237-39. Dr. Andriole, Dr. Catalona's successor as Chief of the University's Division of Urology, could not recall *any* such instance during his 19-year tenure. *Id.* at 2:362.[8]

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[7] The purpose of therapeutic practice is to provide treatment to individuals. By contrast, research is intended to contribute to generalizable knowledge. *See* National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Part A: Boundaries Between Practice and Research (April 18, 1979), *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm.

[8] Petitioners have sought to rely on Dr. Andriole's testimony for the proposition that samples in the biorepository were (...continued)

2. There is also no basis for the assertion that, as a result of the court of appeals' decision, tissue samples in the biorepository may now be used for "embryonic stem cell research," "research on genetic cloning," or other research that RPs oppose on religious or moral grounds. Br. of Amicus Curiae Us Too, Int'l 9-10; *see also* Catalona Pet. 13; Ward Pet. 14 (University "may do whatever it pleases with [the samples] regardless of what it has previously told participants about its purposes"). Petitioners' informed consents stated that the samples could be used for research connected to prostate cancer. There is no prospect (and certainly no evidence) that the University would seek to use samples in the biorepository for any other type of research (or that the samples would even be useful for research that is not related to prostate cancer). If the University ever proposed to do that, the Common Rule would require it to submit any new research protocol to the IRB for approval. The IRB could deny the proposal and could require the University to seek new informed consents from the RPs if a proposal were approved. 45 C.F.R. § 46.109.

Similarly unsupported is Petitioners' assertion that, as a result of the court of appeals' decision, the University will "not hesitate to use research participants' tissues for profit." Catalona Pet. 10. The University has never sold samples from the biorepository for profit; to the contrary, it has

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important for their clinical care, but that testimony referred to the general medical advances that are the object of all medical research, not a specific clinical benefit for the RP Petitioners.

expended millions of dollars to establish and maintain the biorepository as a resource for basic medical research.[9] It is *Petitioners'* position that would encourage bidding wars in which for-profit ventures sought to obtain samples from non-profit biorepositories dedicated to basic medical research. *See* Pet. App. 52a.[10]

3. The court of appeals' decision does not free the University to release the RPs' personal data. Petitioners fail to acknowledge that the RPs' personal data is independently protected by existing laws and regulations. For example, the informed consent documents provide: "I understand that the investigator(s) and the University will take all reasonable measures to protect the confidentiality of my records and my identity will not be revealed in any publication that may result from this project. The confidentiality of my records will be maintained in accordance with applicable state and federal laws." University C.A. App. 3:673. The court of

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[9] Petitioners cite testimony allegedly showing that the University plans to sell samples to the highest bidder, but that testimony shows only that some University officials were concerned that Dr. Catalona seemed willing to deplete the biorepository in return for being listed as a co-author of a publication. Catalona Pet. 11, citing Catalona C.A. App. 157:33.

[10] If Dr. Catalona were to gain control of the samples he could do the very things Petitioners profess to fear the University might do. In the past, Dr. Catalona destroyed samples without the consent of the RPs, transferred samples to other research institutions without RPs' consent, and advocated that RPs be required to waive ownership claims. University C.A. App. 1:87-89, 104-05; 2:241-46, 248-49, 258-60; 3:554, 575, 583, 598, 601, 612, 616.

appeals' decision concerning ownership of the samples does not change the high degree of legal protection afforded to the RPs' personal data.[11]

Petitioners assert that "individuals will be far less likely to consent in the first place" to providing blood and tissue samples for medical research "if they are asked to give up all ownership and control of their own tissues, without any way of knowing how their cells, blood, and DNA will be used." Ward Pet. 15. The decision in this case agrees with every prior judicial decision on point, and there is no indication that these prior decisions have caused individuals to refuse to participate in medical research. Moreover, the RPs in this case *were* told how the samples will be used (for research by University physicians and other researchers related to prostate cancer), and thousands agreed to participate even though they were plainly informed that in doing so they were waiving any claim they might have to the tissues they donated. A comprehensive regulatory system, including provisions for IRB and OHRP oversight, ensures that

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[11] Although Petitioners refuse to acknowledge that "de-identifying" tissue samples (by separating them from the donor's identifying information) is relevant or even possible, de-identification is a basic concept recognized by the Common Rule. *See* 45 C.F.R. §§ 46.101(b)(4), 46.102(f). We leave behind some of our hair, containing our DNA, every time we visit the barber, but no one can link it to us without a reference sample. The same is true of research specimens. They cannot be linked to the donor without access to the donor's genotype as well as the specimen genotype. Accordingly, there is no scientific basis, as well as no legal basis, for the Petitioners' suggestion that the University's ownership of the tissue samples will inevitably lead to a misuse of personal information.

researchers adhere to the limitations set forth in informed consent documents and protect RPs' privacy and personal data.

4. Petitioners' amicus is incorrect in asserting (Us Too Br. 12) that Petitioners contributed samples to be used solely by Dr. Catalona. The informed consent forms and brochures specifically stated that the samples could be used for prostate cancer research conducted by other Washington University physicians as well as for "research with our collaborators at . . . other institutions." University C.A. App. 3:653, 664, 673, 675, 677, 679, 685, 779.

Moreover, the University has informed Dr. Catalona that he is free to request samples from the biorepository and that any such request will be considered on its merits. *Id.* at 2:326-27. The University's Peer Review Panel has granted all three requests for samples submitted by Dr. Catalona. *Id.* at 2:324-25. Thus, there is no reason to conclude that samples in the biorepository will not continue to be available to Dr. Catalona for research related to prostate cancer.

5. Finally, it is undisputed that the "Medical Consent & Authorization" forms requesting that samples be transferred from the biorepository to Dr. Catalona were themselves distributed in violation of the Common Rule. Expert witnesses for *both* sides, and even Petitioner Catalona himself, all agreed that the "Medical Consent & Authorization" was not a valid informed consent document. *Id.* at 1:58, 73, 177-78, 200-01; 2:231-32, 396-97, 450-457. The district court found that the context in which the form was sent is "troubling" and "smacks of undue influence." *See* Pet. App. 51a-52a.

CONCLUSION

The petitions for a writ of certiorari should be denied.

Respectfully submitted,

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APPENDIX

Department of Health & Human Services

Office of the Secretary
Office of Public Health and Science
Office for Human Research Protections
Rockville, Maryland 20852

Nov 29, 2007

Samuel L. Stanley, Jr., M.D.
Vice Chancellor for Research
Washington University School of Medicine
660 South Euclid, Box 8027
St. Louis, MO 63110

Dear Dr. Stanley:

The Office for Human Research Protections (OHRP) has read with interest the district court's opinion in the case of *Washington University v. Catalona, et.al.*, 437 F. Supp. 2d 985 (E.D. Miss. 2006), and the appellate court's opinion affirming the district court's conclusions in *Washington University v. Catalona, et.al.*, 490 F.3d 667 (8th Cir. 2007). In particular, OHRP has noted the courts' statements regarding OHRP's guidance on what language is "exculpatory" under the HHS protection of human subjects regulations, 45 CFR part 46, and thus is regulatorily prohibited from inclusion in a research informed consent document. 45 C.F.R. § 46.116. In order to assist Washington University and its

institutional review board in its future consideration of research informed consent language, I write to clarify OHRP's position as to what language is considered "exculpatory."

OHRP notes that the *Catalona* district court addresses exculpatory language, and OHRP's interpretation of what language qualifies as exculpatory, at several points in its opinion. When presented with OHRP's November 15, 1996 guidance document "'Exculpatory Language' in Informed Consent," which gives examples of language that OHRP considers to be exculpatory, the district court stated that the OHRP guidance is not legally binding upon Washington University, and merely presents an opinion by OHRP regarding what language would be considered exculpatory and thus in violation of the HHS protection of human subjects regulations. *Catalona*, 437 F. Supp. 2d at 998. The district court further stated that the research community's opinion as to what language is "exculpatory" may differ from OHRP's position:

> The governing federal regulation (as to informed consent), 45 C.F.R. § 46.116, only prohibits exculpatory language in the form of a waiver or release from liability.
>
> > "No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."

> It is clear that the only legal obligation WU had was not to include exculpatory language in its informed consent forms which waived any legal rights the RP may have or relieve any party from liability for negligence. Hearing testimony from all experts indicated that the research community consistently understood 45 C.F.R. § 46.116 to bar exculpatory language involving releases from malpractice or other negligence. The OPRR's opinion as to exculpatory language does not govern the informed consents and therefore, does not affect the ownership interest of WU in the materials stored in the GU Biorepository.

Catalona, 437 F. Supp. 2d at 998 (substitution of OHRP for OPRR added). The district court also stated that "as of the date(s) of the hearing, no regulatory agency, including the OHRP, has taken any action against WU regarding the informed consent forms used . . . " *Catalona*, 437 F. Supp. 2d at 992.

OHRP further notes that on appeal, the U.S. Court of Appeals for the 8th Circuit included the following footnote in its opinion affirming the district court's decision, which addresses the informed consent language that Dr. Catalona asserted was exculpatory:

> Because the specific language contained in the consent forms and brochures, as well as the circumstances surrounding the RPs' voluntary decision to donate their biological materials,

> convinces us the RPs intended to make inter vivos gifts of their materials, we find it unnecessary to address the effect or validity of the consent forms' waiver language ("By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate.")

Catalona, 2007 U.S. App. LEXIS 14442, **22.

OHRP agrees with the district court that its guidance document on exculpatory language does not have a legally binding effect upon entities regulated by OHRP. OHRP wishes to clarify that, the district court's opinion notwithstanding, the language included in OHRP's guidance document that is labeled "exculpatory" would be found as such by OHRP during the course of a compliance oversight investigation.

In reference to the district court's statement that to date, OHRP has taken no action against Washington University in reference to the informed consent forms used by the university, OHRP wishes to clarify any possible misconception regarding this point. OHRP notes that in a compliance oversighted investigation that OHRP conducted with Washington University in 2000, OHRP reviewed an informed consent document template that included the following language:

> . . . nor can you claim ownership rights to any medical or scientific product that results from research with your tissue. . . . You will receive no monetary payment nor can you claim ownership rights to any medical or

scientific product that results from research with your tissue. . . .

OHRP did not make a finding of noncompliance regarding this particular language. However, please note that OHRP's failure to make a finding of noncompliance regarding this informed consent language is not an indication that OHRP found this language to be in compliance with the HHS protection of human subjects regulations.

OHRP recognizes the possibility that individuals may have certain legal rights in their excised tissue or other human biological materials, even in the absence of a specific recognition or an affirmative establishment of any such legal rights in these materials by the relevant legal body of a particular jurisdiction. Therefore, except in jurisdictions in which it has been conclusively determined that all research subjects have no legal rights in their excised human biological material, OHRP continues to find language that waives any such legal rights on the part of research subjects to be exculpatory. We believe that, to date, no jurisdictions have conclusively determined that all human subjects have no legal rights in their excised biological material that is used for research purposes.

Please ensure that any such language is removed from informed consent documents currently used at Washington University for human subjects research conducted under the University's Federalwide Assurance with OHRP. If you would like to discuss this issue further, feel free to contact OHRP. Thank you for your commitment to protecting human research subjects.

Sincerely,

/s/

Ivor A. Pritchard, Ph.D.
Acting Director
Office for Human Research
Protections